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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,025	08/26/2003	Nicholas G. Bacopoulos	24852-501 CIP3	6445
35437	7590	01/11/2005	EXAMINER	
MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO			SPIVACK, PHYLLIS G	
666 THIRD AVENUE			ART UNIT	
NEW YORK, NY 10017			PAPER NUMBER	

1614

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/650,025

Applicant(s)

BACOPOULOS ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 41-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,8-40 and 46-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>April 6, 2004</u> . | 6) <input type="checkbox"/> Other: _____  |

Applicants' Response to the Election of Species Requirement filed October 5, 2004 is acknowledged. Applicants have elected with traverse the species suberoylanilide hydroxamic acid (SAHA). No reasons for the traversal are advanced other than the assertion that the election of species is made for the purpose of examination of the claims only and that Applicants maintain the right to have the full scope of the claims examined.

Applicants' comments in response to the request for an election of species are noted. A plethora of compounds of diverse structure are encompassed in the recitation "a hydroxamic acid derivative histone deacetylase (HDAC) inhibitor". A review of some of the various inhibitors contemplated is provided at the bottom of page 44 to page 45 of the specification.

The request for an election of species is still deemed proper and is adhered to. The subject matter initially under consideration are those methods of treating mesothelioma in a subject wherein SAHA is administered, claims 1, 2, 8-40 and 46-61. Those methods drawn to the administration of other compounds are presently withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as directed to non-elected inventions, claims 3-7 and 41-45. Applicants are requested to re-affirm their election when responding to this Office Action.

A Preliminary Amendment filed December 22, 2003 is further acknowledged in which amendments were made throughout the specification that, according to Applicants, add no new matter. No support is provided for any amendment.

An Information Disclosure Statement filed April 6, 2004 is further acknowledged and has been reviewed.

A list of co-pending and related cases of inventor Thomas A. Miller is requested when Applicants respond to this Office Action.

The Amendment filed December 22, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows:

On page 2, the subject matter relating to a first amount of suberoylanilide hydroxamic acid (SAHA) and a second amount of an anti-cancer agent is new matter.

On page 3, the subject matter directed to "cell growth arrest and/or apoptosis" and the recited subject matter "crystal structures", "amorphous structures", "derivatives", "metabolites", "stereoisomers", "structural isomers" and "prodrugs" of the HDAC inhibitors represent new matter.

On page 5, the recitation "natural products, psammaphins and depudecin" is new matter.

On page 29, the recitation "and/or the anti-cancer agents" is new matter.

Applicants are required to cancel the new matter in the reply to this Office Action.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 8-40 and 46-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al., US2003/0161830.

Jackson teaches the administration of modulators of human histone deacetylases for use in the treatment of cancers. However, Jackson additionally teaches the specific inhibitory effect on histone deacetylase activity exhibited by the compound suberoylanilide hydroxamic acid (SAHA). See page 1, paragraph [0008], and page 17, paragraph [0165]. Included among the types of cancers contemplated by Jackson that are treatable by administration of a HDAC modulator is mesothelioma. See page 21, paragraph [0209]. Therefore, in view of the teachings of Jackson, one skilled in the oncology art would have been motivated to treat mesothelioma by administration of SAHA, a compound that is well established in the prior art for its histone deacetylase inhibitory property. Such would have been obvious in the absence of evidence to the contrary because Jackson specifically includes mesothelioma among those cancers that are responsive to a therapeutic regimen comprising administering a modulator of histone deacetylase. SAHA is disclosed in the teaching as a small molecular inhibitor of HDAC. Therefore, it would have been reasonable to expect SAHA to be effective in a treatment modality for mesothelioma. The determination of an optimal dosing regimen, including the mode of administration, dosage form, auxiliary components and dosing schedules, are parameters well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 517-272--0951. The fax phone number for the organization where this application or proceeding is assigned is 571-873-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phyllis G. Spivack  
Primary Examiner  
Art Unit 1614

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**

January 7, 2005